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REMARKS

After entry of the subject amendment, claims 1, 2, 4-6, 8-12, and 28-37 remaining pending the subject application with claims 1 and 12 in independent form. More specifically, in the subject amendment, claim 1 has been amended, claims 3 and 13-27 have been canceled, and claims 29-37 have been added. There is full support in the specification as originally filed for the amendments to the claim 1 and for the added claims. Accordingly, no new matter has been introduced.

Claims 1, 2, 6, 8, 9, and 28 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Wellisz et al. (United States Patent No. 6,302,884). Furthermore, claims 3, 4, 5, and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wellisz et al. in view of Hair (United States Patent No. 6,197,037). Finally, claims 10 and 11 stand rejected under § 103(a) as being unpatentable over Wellisz et al. in view of Pohndorf et al. (United States Patent No. 5,904,683).

The Applicants respectfully traverse the Examiner's § 103(a) rejection of original dependent claim 3 as well as independent claim 12 relying on Wellisz et al. in view of Hair. To this end, the Applicants have amended independent claim 1 to include the limitation of claim 3. As such, independent claim 1, as amended, and independent claim 12 both require a specific structure for the support element and the extension. More specifically, independent claim 1 requires that the support element comprise two support arms that extend in opposite directions from the extension and independent claim 12 requires that the extension extend from the lower side of the support element in such a manner that the support element and the extension form a T-shaped structure in cross section. The first of the two support arms cooperates with the skull and the second of the two support arms cooperates with the bone cover.

As explained throughout the original specification, this particular structural arrangement for the support element and the extension, i.e., the structural arrangement that is claimed in independent claims 1 and 12, is pertinent to the ability of the self-retaining implant of the preferred embodiment to adequately anchor the implant to the

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bone cover, which is ultimately attached to the skull via the implant. More specifically, referring to page 5, lines 5-24 of the original specification, the design of the two support arms extending in opposite directions from the extension (claim 1) and the design of the T-shaped structure formed by the support element and the extension (claim 12) are advantageous because these designs, in combination with the spike (or spikes) that is driven laterally into the bone cover, “allows for particularly reliable securing of the implant to the bone cover” (*see, in particular, page 5, lines 16-22*). Without the two support arms and without the T-shaped structure working in conjunction with the at least one spike, the self-retaining implant may not be suitably secured to the bone cover.

Referring now to page 3 of the Office Action, the Examiner correctly recognizes that Wellisz et al. does not teach a support element having two support arms extending in opposite direction from the extension forming a T-shape with the extension. Then, merely because Hair has two support arms and because Wellisz et al. and Hair are generally “in a similar art”, the Examiner arbitrarily concludes that it would have been obvious to replace the one arm of the device in Wellisz et al. with the two support arms of Hair for joining adjacent bone portions. This is not the case and the Applicant, relying in part on *In re Sang Su Lee*¹, respectfully traverses.

In conjunction with the above, it is respectfully submitted that the Examiner has not established a *prima facie* case of obviousness.² To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest

¹ 277 F.3d 1338 (Fed. Cir. 2002).

² The legal concept of *prima facie* obviousness allocates who has the burden of going forward with production of evidence. The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. MPEP 2142

all the claim limitations. Importantly, the teaching or suggestion to make the claim combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure.³

Under the first criteria of the *prima facie* case of obviousness, the recently decided case of *In re Sang Su Lee* alluded to above clearly defines how suggestion and motivation to combine are determined, and how the knowledge generally available to one skilled in the art is found. The CAFC in *In re Sang Su Lee* reviewed a decision from the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. Both the Examiner and the Board agreed that Sang Su Lee's invention "would have been obvious to one of ordinary skill in the art since the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software," and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial." *Id.* at 1341. However, in this case, the CAFC made it abundantly clear that the Board's and the Examiner's conclusory statements did not adequately address the issue of motivation to modify a reference or motivation to combine references. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. *Id.* at 1343. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." *W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 330, 312-13 (Fed. Cir. 1983). The CAFC went on to state that the "common knowledge and common sense" on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. *In re Sang Su Lee*, 277 F.3d at 1342.

The CAFC also explained in *Zirco*, 258 F.3d at 1385, 59 U.S.P.Q. 2d at 1697, that "deficiencies of the cited references cannot be remedied by the board's general

³ *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

conclusions about what is 'basic knowledge' or 'common sense'". The Board, as well as the Examiner, must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious. *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q. 2d 1453, 1459 (Fed. Cir. 1998). Furthermore, in doing so, the USPTO cannot rely on that which is taught by the Applicant against the Applicant.

In short, *In re Sang Su Lee* emphasizes that the USPTO must, through the efforts of the Examiner, find some suggestion or motivation in the prior art references themselves without relying on subjective belief when making an argument to combine references. Furthermore, this precedential case demands that the Examiner not rely on an overly conclusory analysis when combining references.

Although Wellisz et al. and Hair are, as contended by the Examiner, "in a similar art", this alone does not make it appropriate to combine Wellisz et al. and Hair. Instead, already alluded to above, to appropriately combine the two references, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings.

Simply stated, there is no suggestion or motivation, in either Wellisz et al. or Hair, to combine the two prior art references. Hair merely discloses a self-retaining implant for attaching a bone cover or bone fragment that includes a support element with two support arms having an upper side and a lower side that faces a surface of the bone cover or bone fragment and an extension extending from the lower side of the support element. However, as the Examiner is already aware, Hair **does not** disclose, teach, or otherwise suggest the at least one spike claimed in independent claims 1 and 12. As such, Hair cannot possibly provide the requisite suggestion or motivation to combine its two support arms with the device of Wellisz et al. which requires at least one spike to properly function. Similarly, Wellisz et al. discloses a self-retaining implant for attaching a bone cover or bone fragment that merely includes at least one spike for lateral driving into the bone cover or bone fragment and one arm (which is tab 20). However,

as the Examiner is already aware, Wellisz et al. *does not* disclose, teach, or otherwise suggest a second arm of the support element or, for that matter, a T-shaped structure of the support element and the extension. As such, Wellisz et al. cannot possibly provide the requisite suggestion or motivation to combine its self-retaining implant with at least one spike with the device of Hair.

In sum, Wellisz et al. and Hair teach structures for attaching a self-retaining implant to a bone cover or bone fragment or skull that are mutually exclusive from one another. That is, it is readily apparent that Wellisz et al. uses a securing approach (laterally driven spike and one arm) that is different from the securing approach adopted by Hair (two opposing arms that are disposed to embrace upper and lower sides of bone fragment), and vice versa. To this end, there is no suggestion or motivation in either reference to combine one securing approach with the other and a person of ordinary skill in the art would could find no incentive in either of these references to combine their teachings.

In his general reliance on the prior art and in his rejection of original dependent claim 3 and independent claim 12, the Examiner is overlooking the commercial significance to the medical industry of a self-retaining implant that includes:

- two support arms that extend in opposite directions from an extension; or
- a T-shaped cross-sectional structure of the support element and the extension;

working in conjunction with at least one spike to suitably anchor self-retaining implants to the bone cover and skull.

As a result of the amendment to independent claim 1 and in view of the remarks set forth above relative to both claims 1 and 12, it is respectfully submitted that the Examiner has not established his *prima facie* case of obviousness and that the § 103(a) rejection of original dependent claim 3 (now independent claim1) and independent claim 12 is, therefore, overcome such that these claims are allowable. Furthermore, the remaining claims depend, either directly or indirectly, from the non-obvious features of these independent claims such that these claims are also allowable.

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Finally, Applicant also wishes to note that, relative to new dependent claims 29-37, the prior art of record, including Wellisz et al. and Hair, does not, either alone or in combination, disclose, teach, or even suggest a self-retaining implant having at least one spike that extends from the extension *in a same direction* as a support arm of the support element to appropriately anchor the implant by, in effect, wedging the bone cover or bone fragment between the spike and the support arm.

It is respectfully submitted that the Application is now presented in condition for allowance, which allowance is respectfully solicited.

If necessary, the Commissioner is authorized to charge Deposit Account No. 08-2789 for any additional fees or to credit the account for any overpayment.

Respectfully submitted,

HOWARD & HOWARD ATTORNEYS, P.C.

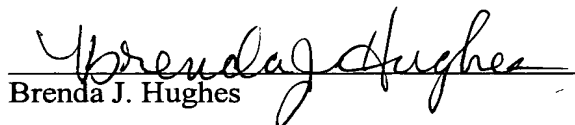
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CERTIFICATE OF MAILING

I hereby certify that the attached **Amendment** for Serial Number 09/921,233, filed August 1, 2001, is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to the **Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450**, on **October 16, 2003**.



Brenda J. Hughes